

REMARKS

Claims 1-56 are currently pending in this application. Applicant has amended claim 10 without additional limitation to place it in better condition for allowance and added new claims 41-56. Reconsideration is respectfully requested in light of the above claim amendments and the following remarks.

Submitted herewith is an amended Figure 5 that corrects typographical errors in the figure. Applicant respectfully submits that no new matter has been added and requests acceptance of the amendment.

The Examiner rejected claim 10 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant has amended claim 10 to recite "the average sinus interval" which finds antecedent basis in claim 8 from which it depends. Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Examiner rejected claims 1-3, 5-15, 25-30, 32, 33, 35-37 and 39 under 35 U.S.C §102(b) as being anticipated by U.S. Patent 5,560,369 to McClure et al. Applicant respectfully traverses this rejection.

Applicant's claimed invention, as recited in pending independent claims 1, 28, 35, 48 and 52 is directed to a cardiac stimulation device and corresponding method. For example, independent claim 1 recites automatically determining the sensing threshold of sinus events and ectopic events and classifying a sensed cardiac event as a sinus event or an ectopic event based on proximity of sensitivity of the sensed cardiac event to the sensing threshold of the sinus events or the sensing threshold of the ectopic events. (Underlining added for emphasis only). Applicant respectfully submits that McClure et al. do not disclose or suggest the recited claim elements.

Rather, McClure et al. disclose a cardiac event and arrhythmia detection system that includes a baseline averager that generates an average baseline signal that is indicative of the average magnitude of an electrogram signal over a predetermined time period. In the system of McClure et al. a change in the average baseline signal of more than a predetermine amount is then deemed to be indicative of arrhythmic activity. (McClure, col. 11, lines 1-7).

Similarly, in the system of McClure et al. an arrhythmia flag signal is generated by the microcontroller when the quotient of the peak (or max) R-wave value divided by the average baseline value exceeds an arrhythmia threshold value (stored, e.g., in the microcontroller). The arrhythmia flag signal may then be used to engage a therapy circuit, e.g., a circuit that issues stimulation and/or defibrillation pulses. (McClure, col. 8, lines 29-26).

Similarly, in the system of McClure et al., if a morphology change value is set (indicating that the average amplitude of an R-wave has reversed polarity), or if there is an increase or decrease in the average amplitude of an R-wave, or a gain change, then there is a high confidence level that a cardiac arrhythmia has begun. (McClure et al., col. 9, lines 10-20).

McClure et al. do not however, disclose or suggest automatically determining the sensing threshold of sinus events and ectopic events and classifying a cardiac event as a sinus event or an ectopic event based on the proximity of the sensitivity of the event to the automatically determined sensing thresholds as recited in claims 1, 28, 35, 48 and 52 of the present invention. (Underlining added for emphasis only). Rather, McClure et al. simply compare an average baseline signal or a morphology change value to a threshold value to indicate a change from rhythmic activity to arrhythmic activity. Accordingly, applicant respectfully submits that claims 1, 28, 35, 48 and 52 are novel and unobvious over McClure et al. and are allowable. Applicant further submits that claims 2-27, 39-34, 36-40, 49-51 and 53-56 that depend from claims 1, 28, 35, 48 and 52 respectively are allowable as are claims 1, 28, 35, 48 and 52 respectively, and for additional limitations recited therein.

Further, newly added independent claim 41 recites a method for use in a cardiac stimulation device comprised in part by automatically determining sensing threshold of the sensed cardiac event, classifying the sensing threshold as a sensing threshold of sinus events or ectopic events as a function of the rhythmic consistency of occurrence of the sensed cardiac event and classifying subsequent sensed cardiac events as a sinus event or an ectopic event based on the proximity of the sensitivity of the cardiac event to the sensing threshold of the sinus events or the sensing threshold of the ectopic events. (Underlining added for emphasis only). Applicant respectfully submits

that the cited references, alone or in combination, do not disclose or suggest the recited claim elements.

Rather, the system of McClure et al. includes a time-out counter that receives a reset signal when the cardiac frequency has a period shorter than a predetermined period of time. However, if the cardiac rhythm deviates from the normal sinus rhythm, such that the cardiac frequency has a period longer than the predetermined period of time, (i.e. if the count of the time out counter exceeds a predetermined count), the time out counter generates a time-out signal. The microcontroller then executes a control program in response to the time-out signal (e.g., to generate the peak signal, arrhythmia flag signal, morphology change signal, etc.). (McClure et al., col. 10, lines 40-59 and col. 19, lines 36-39). McClure et al. do not however, disclose or suggest classifying a sensing threshold as a sensing threshold of sinus events or ectopic events as a function of the rhythmic consistency of occurrence of the sensed cardiac event as recited in claim 41 of the present invention.

Further, as argued above with respect to claims 1, 28, 35, 48 and 52 the system of McClure et al. generates an average baseline signal that is indicative of the average magnitude of an electrogram signal over predetermined time period. McClure et al. then compare the average baseline signal to a threshold value to indicate a change from rhythmic activity to arrhythmic activity or vice versa. (McClure, col. 11, lines 1-7).

McClure et al. do not however, disclose or suggest classifying a sensing threshold as a sensing threshold of sinus events or ectopic events as a function of the rhythmic consistency of occurrence of the sensed cardiac event and classifying a cardiac event as a sinus event or ectopic event based on the proximity of the sensitivity of the sensed event to the sensing threshold of sinus events or ectopic events as recited in claim 41 of the present invention. Applicant therefore submits that claim 41 is novel and unobvious over the cited references and is allowable. Applicant further submits that claims 42-44 that depend from claim 41 are allowable as is claim 41 and for additional limitations recited therein.

Similarly, newly added Independent claim 45 recites a method for use in a cardiac stimulation device comprised in part by "increasing sensitivity of an atrial sensing circuit in response to detection of a predetermined number of occurrences of a

ventricular event that are classified as premature ventricular contractions ... determining regularity of time interval between an atrial event sensed in the sensing window and the ventricular event; and classifying the atrial event as a detected but non-conducted premature atrial contraction ... if the time interval is substantially irregular."

(Underlining added for emphasis only).

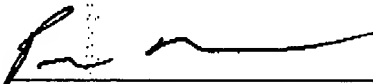
Applicant respectfully submits that the cited references, alone or in combination, do not disclose or suggest the recited claim elements. Applicant therefore submits that claim 45 is novel and unobvious over the cited references and is allowable. Applicant further submits that claims 46-47 that depend from claim 45 are allowable as is claim 45 and for additional limitations recited therein.

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

2-20-04

Date



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